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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE Washington, D.C. 20231

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> > AUG - 8 2002

Timothy E. Nauman Esq Fay, Sharpe, Fagan Minnich & McKee, LLP Cleveland, OH 44114-2516

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EAY, SHARPE, BEALL, FAGAN. MINNICH & MCKEE

LICENSING & REVIEW

CLW2 047

LATE

In re Application of: Seema Garde et al: For Serial No. 09/977,406 **DECISION ON** REQUEST FOR RECONSIDERATION

Filed: October 15, 2001

PHARMACEUTICAL PREPARATIONS AND METHODS FOR INHIBITING

TUMORS

203-305-6384 This is a decision on the REQUEST FOR RECONSIDERATION filed May 14, 2002, responding to the communication (FORM PTOL-456) mailed February 4, 2002

The request has been **DENIED** to the extent indicated below.

42 U.S.C. 2182 states in part "... useful in the production or utilization of special nuclear material or atomic energy". A review of the application file history reveals among other things the use of a radioactive isotope "3H" as disclosed in at least page 53 of the instant specification. Therefore under the directions from the Department of Energy (DOE) this application has been made available to them under 42 U.S.C. 2182 since the following subject matter relates to at least one of the following:

- G. Materials, apparatus and methods concerning isotope and/or radioactive source technology including those utilizing (including responsive to) radioactive sources in:
  - a. Life Sciences such as medicine (diagnostic and therapeutic), ecology, disease and pest control, animal husbandry, etc.
    - b. Industrial processes such as food processing, sterilization, polymer production,
    - c. Investigations of the environment or the earth

H. Instruments employing a radioactive source and/or radioactivity detector in the operation thereof.

Applicant is reminded that a response is due within forty-five days of the mailing date of the communication (FORM PTOL 456). The communication having been mailed February 4, 2002.

Manne P/Hodge

Noanne P/Hodge
Supervisor Legal Instruments Examiner

Licensing and Review

Patent Technology Center 3600

SERIAL NUMBER

FILING DATE

PIRST NAMED APPLICANT

ATTORNEY DOCKET NO

09/977,406

10/15/01

GARDE, ET AL. CLW 2 0147

EXAMINER

TIMOTHY E. NAUMAN, ESQ. FAY, SHARPE, FAGAN, MINNICH & MCKEE, LLP 1100 SUPERIOR AVENUE, 7<sup>TH</sup> FLOOR CLEVELAND, OH 44114-2516

ART UNIT

DATE MAILED:

PAPER NO.

- 8 AUG 2002

## REQUIREMENT FOR STATEMENT UNDER §152 OF THE ATOMIC ENERGY ACT

The subject matter of this application is considered "useful in the production or utilization of special nuclear material or atomic energy."

No patent for any invention "useful in the production or utilization of special nuclear material or atomic energy" may issue unless the applicant files a statement WITHIN THIRTY DAYS from request thereof by the Commissioner of Patents & Trademarks setting forth the full facts surrounding the making or conception of the invention described in the application and whether the invention or discovery was made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the Energy Research and Development Administration or the Department of Energy as required under section 152 of the Atomic Energy Act of 1954, 42 USC §2182.

Applicant is hereby given a period of THIRTY DAYS from the mailing date of this letter to file the required statement under 42 USC §2182. Failure to submit the required statement within the thirty day period will result in ABANDONMENT of the application. The thirty day period is fixed by §2182 of the Act and cannot be extended. Thus, no extension of this period may be obtained under either 37 CFR §1.136(a) or (b).

Joanne P. Hodge

Supervisory Applications Examiner Special Laws Administration

Please direct all written communications regarding this matter to:

The Commissioner of Patents & Trademarks Washington, D.C. 20231

Attention: Licensing & Review

Please direct all telephone calls regarding this matter to: James Samuels, (703) 305-0239

## FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP 1100 SUPERIOR AVENUE, 7th Floor CLEVELAND, OHIO 44114-2518 (216) 861-5582

DATE:

September 9, 2002

TO:

U. S. PATENT AND TRADEMARK OFFICE

ATTENTION:

LICENSING & REVIEW

FACSIMILE NO.:

1 703 305-6384

FROM:

Timothy E. Nauman

RE:

U.S. Application Serial No. 09/977,406

Our Reference: CLW 2 00147

Total number of pages (including this cover sheet): 14

Please call us immediately at (216) 861-5582 if the telecopy you receive is incomplete or illegible. Our facsimile numbers are (216) 241-1666 and (216) 241-5147.

Attached please find a Transmittal and five (5)Declarations Under 42 U.S.C. §2182 for U.S. Serial No. 09/977,406, filed October 15, 2001 (Seema Garde, et al.) for PHARMACEUTICAL PREPARATION AND METHODS FOR INHIBITING TUMORS.

The documents accompanying this facsimile transmission include information from the firm of Fay. Sharpe, Fagan, Minnich & McKee, LLP might be legally privileged and/or confidential. The information is intended for the use of only the individual or entity named on this cover sheet. If you are not the intended recipient, any disclosure, copying, or distribution of these documents, or the taking of any action based on the contents of this transmission, is prohibited. If you have received this transmission in error, these documents should be returned to this firm as soon as possible, and we ask that you notify us immediately by telephone so we can arrange for their return to us without cost to you. CNDATANFAXESNPTOLIC.REV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Seema Garde, et al.

For

PHARMACEUTICAL PREPARATIONS AND

METHODS FOR INHIBITING TUMORS

Serial No.

09/977,4\$6 09/977,406

Filed

October 15, 2001

Group Art Unit

1615

Attorney Docket No.

CLW 2 00147

Assistant Commissioner for Patents

Washington, D.C. 20231

Attention: Licensing and Review

TRANSMITTAL OF STATEMENTS UNDER 42 U.S.C. §2182 (STATEMENT UNDER §152 OF THE ATOMIC ENERGY ACT)

Dear Sir:

Responsive to the Decision on Request for Reconsideration mailed 08 August 2002, applicants submit herewith five (5) Declarations, one signed by each inventor of the subject application, in Response to Notice of Nuclear Material Contained in Application as Recited in 42 U.S.C. §2182.

Respectfully submitted,

FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP

Reg. No. 32,283

1100 Superior Avenue, 7th Floor Cleveland, Ohio 44114-2518

(216) 861-5582

CERTIFICATE OF FACSIMILE

I hereby certify that this Transmittal of Statements Under 42 U.S.C. §2182 and all documents indicated therein as being enclosed, are being transmitted via facsimile to the United States Patent and Trademark Office, Washington, D.C., Attention: Licensing & Review at Final Fax No. 703/305-6384 on September 9, 2002.